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Richard John Bartz  
Southdale Office Centre, Suite 350  
6750 France Avenue South  
Edina, MN 55435

EXAMINER

HUYNH, PHUONG N

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1644

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/038,260

Applicant(s)

NASH ET AL.

Examiner

Phuong Huynh

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Claims 1-30 are pending and are being acted upon in this Office Action.
2. The disclosure is objected to because of the following informality: Cross-reference to related application should have been on the first line of the first page of the specification and not at the title page. Appropriate action is required.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) a method for the production of a microbial adherence inhibitor for administering to food animals to substantially prevent the adherence of targeted colony-forming immunogens in the rumen or intestinal tracts of said food animals which method comprises: inoculating female birds, in or about to reach their egg laying age, with the particular targeted colony-forming immunogen selected from the group consisting of P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, CA antigen from *C. aminophilum*, E coli 0157:H7, Listeria, Salmonella and Campylobacter, allowing a period of time sufficient to permit the production in the bird of antibody to said targeted immunogen, harvesting the eggs laid by the birds, separating the antibody-containing contents of said eggs from the shells and drying said separated antibody-containing contents of said eggs, coating the dry carrier material with the separated antibody-containing contents of said eggs, mixing with dry feed carrier material selected from the group consisting of soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp for preventing the adherence of said microbial from adhering to the rumen of food animal, **does not** reasonably provide enablement for a method for the production of a microbial adherence inhibitor for administration to food animal to substantially prevent the adherence of any targeted "colony-forming immunogens", comprises A) Inoculating female birds, in or about to reach their egg laying age, with any "particular targeted protein-wasting immunogens", any "P antigen" from *P. anaerobius*, any "CS antigen" from *C. sticklandii*, any "CA antigen" from *C. aminophilum*, any *E coli*, any "Listeria antigen" from Listeria, any "Salmonella antigen" from *Salmonella*, or

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any "Campylobacter antigen" from Campylobacter. B) After a period of time sufficient to permit the production in the bird of antibody in the yolk and albumin of the eggs to the targeted immunogen, harvesting the eggs laid by the birds; C) Separating the "anti-yolk and albumin" of said eggs from the shells; D) drying said separating egg antibody yolk and albumin to provide a dried egg antibody product; E) Distributing the resulting dried egg antibody product substantially uniformly through an animal feed or water to provide antibody-containing animal feed or water; and F) Supplying the resulting antibody-containing animal feed or water to food animals to substantially prevent adherence of the targeted immunogen in the intestinal tract of the animal; (2) the said method wherein any colony-forming immunogen is one known to decrease any animal's ability to utilize dietary protein, (3) the said method including providing any dry weight carrier material, said drying of the separated antibody-containing contents of said eggs is achieved by coating the dry carrier material with the separated antibody-containing contents of said eggs, (4) the said method wherein providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp for a method of promoting the growth food animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a method for the production of a microbial adherence inhibitor for administration to food animals to substantially prevent the adherence of colony-forming immunogens by inoculating female bird with the specific bacteria as immunogen selected from the group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli* serogroup 0157: H7, *Salmonella*, and *Campylobacter*, harvest the eggs laid by the birds, separating the antibody-containing contents of said harvested eggs from the shells, drying the separated antibody, mix and pasteurize the whole egg prior to mixing with the animal feed or

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water with said egg antibody to prevent the adherence of the specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

The specification does not teach how to produce any microbial adherence inhibitor other than the ones mentioned above because the terms "colony-forming immunogens", "P antigen", "CS antigen", "CA antigen", "Listeria antigen", "Salmonella antigen" and "Campylobacter antigen" do not convey structure without the specific amino acid sequence (SEQ ID NO).

Stryer *et al* teach that a protein is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformation of the protein (See enclosed appropriate pages).

Further, given the indefinite number of undisclosed immunogens or antigens such as any "P antigen", "CS antigen", "CA antigen", "Listeria antigen", "Salmonella antigen" and "Campylobacter antigen", there is insufficient working examples demonstrating that microbial adherence inhibitor such as any avian antibody produced by inoculating the birds with any undisclosed immunogens or antigen is effective for inhibiting the ability of any organism to adhere to the rumen of or intestinal tracts of animals to reduce the ability of bacteria such as *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli* serogroup 0157: H7, *Salmonella*, and *Campylobacter* to multiply. It is well known that not all immunogen or antigen on any given microorganism plays a role in adherence and colonizing the rumen or intestinal tract of any animal. Even if the immunogen is known, the antibody generated from the specific immunogen can only be specific to that immunized immunogen. For example, immunizing an egg-laying hen with bacteria *P anaerobius* can generate antibody only specific to said bacteria and under no circumstance can the hen generate antibody to the other bacteria such as *E coli*. Further, a bacterium has more than one antigen and not all antigens play a roll in adherence. In the absence of guidance as to which specific antigen such as chemical and amino acid sequence from which specific bacteria, bird antibody generated from inoculating with any antigen is not effective for preventing the adherence of any bacteria since the antibody is not specific.

Kuby *et al* teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

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Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular). Since the amino acid sequence of the immunogen is unknown, it follows that the antibody generated from any immunogen is not specific, in turn; the microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony-forming protein wasting organisms is not enabled. Given the indefinite number of undisclosed immunogen, it is unpredictable which microbial adherence inhibitor produced by immunizing a hen with any undisclosed immunogen will have the same antibody specificity as the antibody that binds specifically to protein-wasting immunogen such as *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E coli*, *Listeria*, *Salmonella* and *Campylobacter* in turn, would be useful for any purpose.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

5. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of a method for the production of a microbial adherence inhibitor for administration to food animal to substantially prevent the adherence of any targeted "colony-forming immunogens". comprises A) Inoculating female birds, in or about to reach their egg laying age, with any "particular targeted protein-wasting immunogens", any "P antigen" from *P. anaerobius*, any "CS antigen" from *C. sticklandii*, any "CA antigen" from *C. aminophilum*, any *E coli*, any "Listeria antigen" from *Listeria*, any "Salmonella antigen" from *Salmonella*, or any "Campylobacter antigen" from

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Campylobacter, B) After a period of time sufficient to permit the production in the bird of antibody in the yolk and albumin of the eggs to the targeted immunogen, harvesting the eggs laid by the birds; C) Separating the "anti-yolk and albumin" of said eggs from the shells; D) drying said separating egg antibody yolk and albumin to provide a dried egg antibody product; E) Distributing the resulting dried egg antibody product substantially uniformly through an animal feed or water to provide antibody-containing animal feed or water; and F) Supplying the resulting antibody-containing animal feed or water to food animals to substantially prevent adherence of the targeted immunogen in the intestinal tract of the animal; (2) the said method wherein any colony-forming immunogen is one known to decrease any animal's ability to utilize dietary protein, (3) the said method including providing any dry weight carrier material, said drying of the separated antibody-containing contents of said eggs is achieved by coating the dry carrier material with the separated antibody-containing contents of said eggs, (4) the said method wherein providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp for a method of promoting the growth food animals.

The specification discloses only a method for the production of a microbial adherence inhibitor for administration to food animals to substantially prevent the adherence of colony-forming immunogens by inoculating female bird with the specific bacteria as immunogen selected from the group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli* serogroup 0157: H7, *Salmonella*, and *Campylobacter*, harvest the eggs laid by the birds, separating the antibody-containing contents of said harvested eggs from the shells, drying the separated antibody, mix and pasteurize the whole egg prior to mixing with the animal feed or water with said egg antibody to prevent the adherence of the specific immunogen in the intestinal tracts of the animal and thereby promote the growth of the animals.

Other the specific organisms mentioned above for a method of for the production of a microbial adherence inhibitor for administration to food animals to substantially prevent the adherence of colony-forming organisms, there is inadequate written description about the structure associated with function of (1) any "colony-forming immunogens", any "P antigen" from *P. anaerobius*, any "CS antigen" from *C. sticklandii*, any "CA antigen" from *C. aminophilum*, any *E coli*, any "Listeria antigen" from *Listeria*, any "Salmonella antigen" from *Salmonella*, or any "Campylobacter antigen" from *Campylobacter* for the claimed methods because the term immunogen and antigen without the specific amino acid sequence or SEQ ID

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NO: has no structure. Further, inoculating any female bird with the specific organisms can only produce microbial inhibitor such as avian antibody to said organisms. Given the indefinite number of undisclosed "colony-forming immunogens" or "antigen", the method for the production of any microbial adherence inhibitor is not adequately described.

Since the specification discloses only a method of producing fowl egg antibodies to six colony-forming immunogens such as bacteria selected from the group consisting of *P. anaerobius*, *C. Sticklandii*, *C. aminophilum*, *E coli* serogroup 0157: H7, *Salmonella*, and *Campylobacter* where such immunogens colonize the rumen or alimentary tract of food animals, causing, robbing food animals nutrients, as well as food borne illness in humans, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "particular targeted protein-wasting immunogen" in claim 1 is ambiguous and indefinite because it is not clear which particular targeted protein-wasting immunogen to be used for inoculating the bird. One of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention.

The limitation "said colony-forming immunogen" in claims 2-5 has no antecedent basis in base claim 1. Base claim 1 recites "colony-forming immunogens". Appropriate action is required.



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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 4-5, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No. 5,080,895 (Jan 1992; PTO 1449).

The '895 patent teaches a method for the production of a microbial adherence inhibitor such as bird antibody that binds to E coli for promoting the growth of food animals by preventing diarrhea (dietary protein wasting caused by diarrhea due to the presence of E coli) in livestock by inoculating an egg laying female birds such as hen against a selected immunogen such as bacterium E coli (See column 5, lines 29-30, in particular), after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to the immunized immunogen in the yolk and the albumin of the eggs (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both (See column 6, lines 19-20, in particular), drying the separated egg antibody by the process such as spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular), distributing the resulting dried egg antibody product as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of food animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). Thus, the reference teachings anticipate the claimed invention.

10. Claims 1-2, 4-5, 17, 20, 23, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 4,748,018 (May 31, 1988; PTO 1449).

The '018 patent teaches a method for the production of a microbial adherence inhibitor such as bird antibody such as IgY antibody that binds to colony-forming immunogens *E coli*, *Listeria*, *Salmonella* and/or *Campylobacter* that inherently prevent the adherence of said colony-forming immunogens from adhere to the rumen or intestinal tracts (See column 5, lines 1-30,

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column 6, line 22-25, in particular). The reference method comprises inoculating an egg laying female birds such as the hen in their egg laying age with the reference immunogen or immunogens such as bacterium as *E coli*, *Listeria*, *Salmonella* and *Campylobacter*, allowing a period of time sufficient to permit the production of bird antibody that binds to the targeted immunogens, collecting the egg laid by the hen, purifying the reference antibody and lyophilizing or drying the separated egg antibody (See column 9, lines 17 bridging column 10, lines 1-29, in particular). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen or antigens is useful for a method of passive immunity (See abstract, in particular). The intended use of the product produced by the claimed method has no patentable weight because a product can have more than one use. Thus, the reference teachings anticipate the claimed invention.

11. Claims 1-2, 4-5, 17, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugita-Konishi *et al* (Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) or Yokoyama *et al* (Vaccine 16(4): 388-93, Feb 1998; PTO 892).

Sugita-Konishi *et al* teach a method of producing a microbial adherence inhibitor such as IgY antibody that binds to *Salmonella* that inhibits the adhesion of *Salmonella* to human intestinal cells (Caco 2) in culture (See abstract, and Materials and Methods, in particular). The reference method comprises immunizing female birds with *Salmonella* colony-forming immunogen that is responsible for salmonella enteritidis, after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to *Salmonella*, purifying the reference antibody and drying the separated antibody (See Materials and methods, in particular). The reference *Salmonella* is known to cause food borne illness in humans (See Introduction, in particular). Claim 17 is included in this rejection because *Salmonella* a form of *E coli*.

Yokoyama *et al* teach a method of producing a microbial adherence inhibitor such as chicken egg yolk homotypic antibodies specific for an colony-forming immunogen such as the outer membrane proteins (OMP) of *Salmonella*. The reference method comprises immunizing female birds with outer membrane proteins (OMP) of *Salmonella* colony-forming immunogen, after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to *Salmonella*, purifying the reference antibody and drying the separated antibody (See Materials

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and methods, in particular). The reference microbial adherence inhibitor inhibits the adhesion of *Salmonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by *Salmonella enteritidis* and *S. typhimurium* (See abstract, (See abstract, and Materials and Methods, in particular). The reference *Salmonella* is known to cause food borne illness in humans (See Introduction, in particular). Claim 17 is included in this rejection because *Salmonella* a form of *E coli*. Thus, the reference teachings anticipate the claimed invention.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-3, 8, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Krause *et al* (Appl Environ Microbiol 62(3): 815-21; 1996, PTO 1449).

The teachings of the '895 patent have been discussed supra.

The claimed invention in claim 3 differs from the teachings of the reference only that the method wherein the protein-wasting immunogen is selected from the group consisting of *P anaerobius*, *C. sticklandii* and *C aminophilum*.

The claimed invention in claim 8 differs from the teachings of the reference only that the method wherein the protein-wasting immunogen is P antigen from *P. anaerobius*.

The claimed invention in claim 11 differs from the teachings of the reference only that the method wherein the protein-wasting immunogen is CS antigen from *C. sticklandii*.

The claimed invention in claim 14 differs from the teachings of the reference only that the method wherein the protein-wasting immunogen is CA antigen from *C. aminophilum*.

Krause *et al* teach *Peptostreptococcus anaerobius*, *Clostridium sticklandii*, and *Clostridium aminophilum* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilum* in livestock.

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Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the E coli as taught by the '895 patent for the immunogen such as *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* as taught by Krause *et al* for a method for the production of a microbial adherence inhibitor such as fowl antibody that binds to *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* and prevent the adherence of *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* in the rumen or intestinal tracts of food animals as taught by the '895 patent and Krause *et al*. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Krause *et al* teach that rumen bacterial such as *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* are responsible for nutrition depletion in the growth of livestock and despite adding feed additive such as monensin, *Clostridium aminophilum* persists in the rumen (See abstract, page 819, column 1, first full paragraph, in particular). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular).

14. Claims 6-7, 9-10, 12-13, 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (Jan 1992; PTO 1449) in view of Krause *et al* (Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892) as applied to claims 1-3, 8, 11 and 14 mentioned above and further in view of US Pat 6,086,878 (Jul 2000, PTO 1449) and US Pat No. 4,166,867 (Sept 1979, PTO 1449).

The combined teachings of the '895 patent and Krause have been discussed supra.

The claimed invention in claims 6, 9, 12, and 15 differs from the combined teachings of the references only that the method includes providing a dry carrier materials, coating the dry carrier material with the separated antibody-containing contents of said eggs.

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The claimed invention in claims 7, 10, 13, and 16 differs from the combined teachings of the references only that the method includes providing dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk from the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat any of the animal feed such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the microbial adherence inhibitor such as the IgY antibody that binds specifically to *E coli* as taught by the '895 patent or to IgY antibody that binds specifically to *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* as taught by the '895 patent and Krause et al wherein the antibody has been spray-dried as taught by the '878 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent

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teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). Krause *et al* teach immunogen such as *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* are responsible for nutrition depletion and the growth of livestock (See entire document) in livestock. The '895 patent teaches that adding bird antibody (IgY) against any desired immunogen of interest as a feed additive can promote the growth of food animals by preventing diarrhea in livestock since the method of making bird antibody to any immunogen (bacteria) of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27). The recitation of drying said antibody yolk and albumin by coating the carrier material with said antibody yolk and albumin is an obvious variation of the teachings of the references.

15. Claims 1, 6-7, 17-25 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 4,748,018 (May 31, 1988; PTO 1449) in view of US Pat 6,086,878 (Jul 2000, PTO 1449) and US Pat No. 4,166,867 (Sept 1979, PTO 1449).

The teachings of the '018 patent have been discussed supra.

The claimed invention in claims 6, 18, 21, 24 differs from the combined teachings of the references only that the method includes providing a dry carrier materials, coating the dry carrier material with the separated antibody-containing contents of said eggs.

The claimed invention in claims 7, 19, 22, 25 and 30 differs from the combined teachings of the references only that the method includes providing dry feed carrier material form a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and

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cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat any of the animal feed such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the microbial adherence inhibitor such as the IgY antibody that binds specifically to *E coli* as taught by the '895 patent or to colony-forming immunogens *E coli*, *Listeria*, *Salmonella* and/or *Campylobacter* as taught by the '018 patent wherein the antibody has been spray-dried as taught by the '878 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). The '018 patent teaches that the avian antibody produced by domesticated fowl which has been immunized against any antigen or antigens is useful for a method of passive immunity (See abstract, in particular). The recitation of drying said antibody yolk and albumin by coating the carrier material with said antibody yolk and albumin is an obvious variation of the teachings of the references.

16. Claims 1, 6-7, 17-19 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugita-Konishi *et al* (Biosci Biotechnol Biochem 60(5): 886-8, May 1996; PTO 892) or Yokoyama *et al* (Vaccine 16(4): 388-93, Feb 1998; PTO 892) in view of US Pat 6,086,878 (Jul 2000, PTO 1449) and US Pat No. 4,166,867 (Sept 1979, PTO 1449).

The teachings of the Sugita-Konishi *et al* and Yokoyama *et al* have been discussed supra.

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The claimed invention in claims 6, 18, 24 and 27 differs from the combined teachings of the references only that the method includes providing a dry carrier materials, coating the dry carrier material with the separated antibody-containing contents of said eggs.

The claimed invention in claims 7, 19, 25 and 28 differs from the combined teachings of the references only that the method includes providing dry feed carrier material form a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat any of the animal feed such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent with the microbial adherence inhibitor such as the IgY antibody that binds specifically to *Salmonella* as taught by Sugita-Konishi *et al* or Yokoyama *et al* wherein the antibody has been spray-dried as taught by the '878 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls



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provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). Sugita-Konishi *et al* teach that the a method of producing a microbial adherence inhibitor such as IgY antibody that binds to *Salamonella* is useful for inhibiting the adhesion of *Salamonella* to human intestinal cells such as Caco 2 in culture (See abstract, and Materials and Methods, in particular). Yokoyama *et al* teach that microbial adherence inhibitor that inhibits the adhesion of *Salamonella* to Hella cells and is useful as oral passive vaccine against Salmonellosis caused by Salmonella enteritidis and S. typhimurium (See abstract, (See abstract, and Materials and Methods, in particular). The recitation of drying said antibody yolk and albumin by coating the carrier material with said antibody yolk and albumin is an obvious variation of the teachings of the references.

17. No claim is allowed.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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19. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

June 2, 2003

*Christina Chan*  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600